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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,712	03/31/2000	DONALD H. RUBIN	01123.0004	8103

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EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 02/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/509,712	RUBIN ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2002 and 09 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *1-23 and 25-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24,30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Acknowledgment of the amendment made on page 1 of the specification presented in paper no. 17 is made and the changes have been entered. In paper no. 16, applicant amended claim 30 and added new claim 31. Claims 1-31are pending, claims 1-23, 25-29 are withdrawn from consideration due to a non-election of invention and claims 24, 30 and 31 are under consideration to the extent the claims read on elected SEQ ID NO: 75, as all other SEQ ID NO's in the claims are drawn to a non-elected invention.

Although newly presented claim 31 requires additional steps within the method, the concept of determining how and if a compound affects viral infection are the same as that presented in original claims 24 and 30. Therefore, any rejection of record that is applied against claim 24 and 30 is also applicable against newly presented claim 31.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24, 30 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

Applicant describes the invention in detail and explains that cells containing a marker gene that has inserted itself into the cellular gene necessary for the survival of the cell infected with virus will survive, while those cells that do not have the properly integrated gene will not survive. In response to the rejection involving homologs, applicant outlines the procedure

discussed in the specification for generically identifying homologs and concludes that homologs are confirmed by their functionality.

Applicant's concise explanation of the invention is appreciated, but does not obviate the rejection of record for determining the nexus between the cellular gene, SEQ ID NO: 75 and the effect the compound has on viral infection. Applicant's explanation only further confuses the issue. Applicant has carefully explained that only cells expressing the properly integrated gene will survive viral infection. Therefore, it appears that the gene is required for survival of the cells and not just required for viral propagation within the cells since cells expressing the gene are resistant to viral infection and those that do not have the gene are fatally non-resistant. This concept is contradictory to the limitation in the claims, requiring that the gene product is only necessary for reproduction of the virus in the cell. Further, a compound that decreases or inhibits gene expression that is required for the survival of resistant cells in the presence of virus does not reflect inhibition of viral replication in naturally, non-resistant cells. Therefore, the nexus between the cellular gene, SEQ ID NO: 75 and how the compound affects viral infection remains unclear.

Applicant's explanation of sequence homologs has been considered, but is found unpersuasive because the metes and bounds of the claimed homologs are still not clearly defined by applicant's explanation or the disclosure. Neither a homologous function nor structure of SEQ ID NO: 75 have been identified for the specific sequence. Therefore, the skilled artisan would be unable to identify a homolog of SEQ ID NO: 75 and these compounds remain vague and indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24, 30 and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection, maintained for reasons of record.

Applicant argues that it is standard in the art to identify sequences comprising a certain percentage of homology with a specific sequence, i.e. SEQ ID NO: 75. These homologs are then assayed by conventional methods to determine whether requires functionality is retained.

Applicant's arguments have been carefully considered, but are found unpersuasive. As discussed in the rejection, the claimed homologs encompass sequences that are structurally and functionally unrelated to SEQ ID NO: 75. Further, the claim does not specify how homologs bear resemblance to SEQ ID NO: 75. Therefore, the resemblance could be structural and/or functional. The skilled artisan would be unable to readily structurally identify a homolog of SEQ ID NO: 75.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, there is not even identification of

any particular portion of the structure of SEQ ID NO: 75 that must be conserved in the claimed homologs. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemi chemical structure of the encompassed genus of homologs, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the isolated sequence set forth in SEQ ID NO: 75, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 24, 30 and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record.

With regard to the relationship between the compound, the cellular gene and the gene product, applicant asserts that the gene product is necessary for viral growth in the cell, but not the survival of the cell. A decrease in expression of the gene product classifies compounds used in the method as antiviral agents.

Applicant's explanation has been carefully considered, but is found unpersuasive because the gene products are required for the survival of the infected cells and not merely the replication of viral species. This fact is established by applicant's explanation that cells that do not express the gene succumb to viral infection, while those cells that express the gene are resistant. Therefore, the nexus between the components in the claims remains confusing. . Further, it is maintained that the skilled artisan would be unable to make or identify homologs of SEQ ID NO: 75 for reasons discussed above.

Applicant also states that the instant method is drawn to *in vitro* screening methods of compounds and asserts that a decrease or elimination of gene expression indicates anti-viral activity to be further assayed for *in vivo* applicability.

Applicant's arguments have been carefully considered, but are found unpersuasive because cell survival is directly dependent upon gene expression in the presence of virus. A

compound that decreases or inhibits gene expression that is required for the survival of resistant cells in the presence of virus does not reflect inhibition of viral replication in naturally, non-resistant cells. There is no evidence that the depression of the gene product by the compound has detrimental effects on viral infectivity. There are also no working examples that demonstrate the association between a compound, a cellular gene, and a gene product that is indicative of an antiviral effect.

Applicant points out that the prior to the instant invention the viral art did not correlate SEQ ID NO: 75 with viral infection.

Applicant's statement has been carefully considered, but since there is no direct link between viral infection and zinc finger transcription factors, rat U3 gene trap nucleic acids, or nucleic acid sequences from Chinese hamsters, it is the burden of applicant to establish a direct correlation between these genes an viral infection to enable the skilled artisan to practice the instant invention. It has not been established that the instant gene product is directly associated with viral infection. Therefore, the nature of the invention, drawn to identifying antiviral compounds using the instant method, is unpredictable because applicant has not identified an antiviral compound using the instant method.

For these reasons, it is maintained that the skilled artisan would be unable to make or use the invention without an undue quantity of experimentation.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
February 24, 2003

JAMES HOUSEL 2/24/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600